

Claims

1. A stent for use within a body lumen of a patient, comprising:
- (a) a coil segment defining a lumen therethrough and including a distal portion, a middle portion, and a proximal portion, the coil segment comprising a wound element including one or more windings spaced from each other along at least a portion of the length of the coil segment and being reducible in width at least to an extent needed to pass the stent into the body lumen of the patient by winding the wound element, each of the distal and proximal portions including a diameter greater than a diameter of the middle portion when the stent is positioned and left within the body lumen of the patient; and
- (b) a flexible polymer material encapsulating at least a portion of the coil segment and disposed between the spaced windings of the wound element to form an imperforate flexible webbing between the windings that inhibits ingrowth of body tissue between the windings when the stent is placed within the body lumen of the patient while also maintaining the lumen of the coil segment open.
2. The stent of claim 1 wherein the wound element comprises a wire of a biocompatible material.
3. The stent according to claim 2 wherein the biocompatible material is selected from the group consisting of stainless steel, titanium, a nickel-titanium alloy, or a polymer.
4. The stent of claim 2 wherein a cross-sectional area of the wire is in the range of from about 7.9×10^{-3} millimeters² to about 7.1 millimeters².
5. The stent of claim 1 wherein the spaced windings are separated by a distance in the range of from about 0.5 millimeters to about 10 millimeters.
6. The stent of claim 1 wherein each of the distal and proximal portions includes one or more hooks to permit connection to a delivery system.

7. The stent of claim 1 wherein the flexible polymer material comprises a low durometer silicone.

8. The stent of claim 7 wherein the low durometer silicone has a Shore A hardness in the range of from about 0 durometers to about 60 durometers.

9. A method of attaching a stent to a delivery system, comprising:

(a) providing a stent for use within a body lumen of a patient, comprising:

a coil segment defining a lumen therethrough and including a distal portion, a middle portion, and a proximal portion, the coil segment comprising a wound element including one or more windings spaced from each other along at least a portion of the length of the coil segment and being reducible in width at least to an extent needed to pass the stent into the body lumen of the patient by winding of the wound element, each of the distal and proximal portions including a diameter greater than a diameter of the middle portion when the stent is positioned and left within the body lumen of the patient, and

a flexible polymer material encapsulating at least a portion of the coil segment and disposed between the spaced windings of the wound element to form an imperforate flexible webbing between the windings that inhibits ingrowth of body tissue between the spaced windings when the stent is placed within the body lumen of the patient while also maintaining the lumen of the coil segment open;

(b) providing a delivery system comprising:

a first element having an outer diameter smaller than the diameter of the middle portion of the stent and including a first end, a second end, and a connection member extending out from the first end, and

a second element including a first end, a second end, and a connection member extending out from the first end, at least one of the first and second elements of the delivery system being rotatable;

(c) placing the first element of the delivery system within the lumen of the coil segment;

(d) attaching the connection member of the first element to the proximal portion of the stent;

(e) attaching the connection member of the second element to the distal portion of the stent; and

(f) rotating at least one of the first and the second elements to further wind the wound element to reduce the width of the stent at least to an extent needed to pass stent into the urethra of the patient.

10. The method of claim 9 wherein the connection member of the first element comprises an arm extending radially outward from the first end and includes an opening sized to receive a hook extending from the proximal portion of the stent.

11. The method of claim 9 wherein the connection member of the second element comprises an arm extending radially outward from the first end and includes an opening sized to receive a hook extending from the distal portion of the stent.

12. The method of claim 9 wherein the second element defines a lumen extending therethrough and sized to receive the first element.

13. A method of positioning a stent within a body lumen of a patient, comprising:

(a) providing a stent and a delivery system,
the stent comprising:

a coil segment defining a lumen therethrough and including a distal portion, a middle portion, and a proximal portion; the coil segment comprising a wound element including one or more windings spaced from each other along at least a portion of the length of the coil segment and being reducible in width at least to an extent needed to pass the stent into the body lumen of the patient by winding of the wound element, each of the distal and proximal portions including a diameter greater than a diameter of the middle portion when the stent is positioned and left within the body lumen of the patient, and

a flexible polymer material encapsulating at least a portion of the coil segment and disposed between spaced windings of the wound element to form an imperforate flexible webbing between the windings that inhibits ingrowth of body tissue between the

spaced windings of the stent when placed within the body lumen of the patient while maintaining the lumen of the coil segment open, and the delivery system comprising:

a first element having an outer diameter smaller than the diameter of the middle portion of the stent and including a first end, a second end, and a connection member extending out from the first end and attached to the proximal portion of the stent, the first element disposed within the lumen of the coil segment, and

a second element including a first end, a second end, and a connection member extending out from the first end and attached to the distal portion of the stent, at least one of the first and the second elements of the delivery system being rotatable, the stent being wound onto at least a portion of the first element to reduce the width of the stent at least to an extent needed to pass the stent into the urethra of the patient;

(b) inserting the delivery system with the attached and wound stent into the urethra of the patient;

(c) positioning the stent within the prostatic urethra of the patient with the proximal portion located within the bladder opening and the distal portion located proximal to the external sphincter;

(d) rotating at least one of the first and second elements of the delivery system to at least partially unwind the stent;

(e) releasing the stent from the connection members of the delivery system; and

(f) removing the delivery system from the patient's urethra.

14. The method of claim 13 wherein the connection member of the first element comprises an arm extending radially outward from the first end and includes an opening sized to receive a hook extending from the proximal portion of the stent.

15. The method of claim 13 wherein the connection member of the second element comprises an arm extending radially outward from the first end and includes an opening sized to receive a hook extending from the distal portion of the stent.

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Category	Frequency	Percentage	Mean	Standard Deviation	Minimum	Maximum
1. Very High	10	10.0	1.0	0.0	1.0	1.0
2. High	20	20.0	2.0	0.0	2.0	2.0
3. Moderate	30	30.0	3.0	0.0	3.0	3.0
4. Low	40	40.0	4.0	0.0	4.0	4.0
5. Very Low	50	50.0	5.0	0.0	5.0	5.0